

## **REMARKS/ARGUMENTS**

### **Telephone Interview**

Applicants greatly appreciate the courtesy that the Examiner extended to their representative during the telephone interview held on June 8, 2010. The discussions during the telephone interview have been taken into consideration herein.

### **Status of the Claims**

Claims 20-22, 28-29, 34-39, and 41-55 are pending in the subject application, among which claims 20, 36, and 46 are independent. Claims 1-19, 23-27, 30-33, and 40 have been previously cancelled without prejudice. Independent claim 1 has been amended to recite additional subject matter supported by previously presented claim 1. New claims 53-55 have been added to recite additional subject matter disclosed in the original specification. No claim has been amended herein.

Reconsideration of the subject application in view of the above amendments and the following remarks is hereby respectfully requested.

### **Overview of the Office Action**

Claims 20-22, 28-29, 34-39, 41-43, and 45-52 have been rejected under 35 U.S.C. §102(e) as anticipated by US 6,761,719 (Justis).

Claim 44 has been rejected under 35 U.S.C. §103(a) as unpatentable over Justis, in view of US 6,296,643 (Hopf).

### **Summary of the Subject Matter Disclosed in the Specification**

The following descriptive details are based on the specification. They are provided only for the convenience of the Examiner as part of the discussion presented herein, and are not intended to argue limitations which are unclaimed.

The subject application discloses a method for correcting spinal deformities, including that of scoliosis, kyphosis, or lordosis in a patient's spine, so that the deformed spine portion can assume a normal degree of kyphosis and lordosis. The spinal correction in the subject application is carried out using a superelastic rod that comprises a superelastic material having a transition temperature ( $A_f$ ) within the range of human body temperature. The superelastic rod has "a pre-contoured shape of a normal degree of kyphosis and lordosis of at least a portion of the patient's spine."

When using the superelastic rod to correct the patient's spinal deformities, the pre-contoured rod is deformed "to conform to a deformed portion of the patient's spine." For example, such operation can be handled by an orthopedic surgeon during an orthopedic procedure, such as through bending, twisting, or otherwise manipulating the pre-contoured rod so that it is deformed to have substantially the same shape of the deformed spine portion to be corrected. The deformed rod thus deviates from the pre-contoured shape of a normal degree of kyphosis and lordosis of the spine and assumes the shape of a deformed kyphosis and lordosis of the patient's spine to be corrected. Such deformed rod is then mounted onto "the patient's spine including the deformed portion," such as by an orthopedic surgeon during an orthopedic procedure.

After the deformed rod is secured in place on the patient's deformed spine, the deformed rod is subject to the patient's body temperature. Under the patient's body temperature, the superelastic material in the deformed rod, which has a transition temperature ( $A_f$ ) within the range of human body temperature, undergoes transition to an austenite phase. As a result of the phase transition, the deformed rod returns to the pre-contoured shape of a normal degree of kyphosis and lordosis of the spine. When doing so, the deformed rod generates a correction force for correcting patient's deformed spine portion. For example, the correction force is

applied to the patient's deformed spine portion and thus forces such deformed spine portion to assume the same shape of the deformed rod, as such deformed rod returns to its pre-contoured shape. The spinal correction continues until the deformed rod returns to its pre-contoured shape.

When the deformed rod returns to its pre-contoured shape, the patient's deformed spine portion (mounted to the deformed rod), is brought to the pre-contoured shape of the rod and thereby assumes a normal degree of kyphosis and lordosis of the spine. As a result, the spinal deformities (including that of scoliosis, kyphosis, or lordosis) can be fully or substantially fully corrected, so that the patient's spine will have a normal degree of kyphosis and lordosis.

In the subject application, the spinal correction can be carried out automatically once the deformed rod is mounted onto the deformed portion of the patient's spine to be corrected. No further intervention is required from either an orthopedic surgeon or the patient to correct the spinal deformities in the patient's spine. Additionally or alternatively, the spinal correction according to the subject application can be carried out regardless whether the patient is engaging in any body movement. For example, the spinal correction according to the subject application can be carried out even when the patient is asleep at night.

### **Discussion of the Cited Art**

Justis teaches a device for flexibly stabilizing a user's spine. The stabilizing device of Justis includes a spinal rod 302 formed of a shape-memory material that exhibits pseudoelastic behavior at about human body temperature. The spinal rod 302 has an initial or "memorized" shape (see Fig. 13a of Justis), as well as a different shape (see Fig. 13b) when deformed through the imposition of stress onto the spinal rod 302. When the spinal rod 302 is reshaped or deformed at a temperature above the transformation temperature  $A_s$ , the spinal rod 302 will automatically recover toward its initial shape when the stress is removed. (See col. 12, ll. 16-22 of Justis.)

For example, the spinal rod 302 in Justis is secured to the vertebrae V while in a substantially unstressed, initial configuration, where virtually all of the shape-memory material is in an austenitic state. Upon the imposition of stress onto the spinal rod 302, caused by relative movement between the vertebrae V, a portion of the shape-memory material in the spinal rod 302 will be transformed into reversible stress-induced martensite. When the stress is removed, the shape-memory material in the spinal rod 302 is transformed back into austenite. (See col. 12, ll. 23-32 of Justis.)

Justis's spinal rod 302 merely provides flexible support to a weak spinal column of a user so as to stabilize such a weak spinal column. The shape change of the spinal rod 302 during its normal use is mainly caused by the user's body movement. The spinal rod 302 in Justis operates to support the user's spine during various body movements.

There is no discussion in Justis about correcting deformities of scoliosis, kyphosis, or lordosis in a patient's spine. If Justis's spinal rod 302 is used on a patient with a deformed spine portion (e.g., that of scoliosis, kyphosis, or lordosis in a patient's spine), such deformed spine portion of the patient cannot be corrected to assume a normal degree of kyphosis and lordosis. Consequently, Justis differs from the subject application, which provides a method for correcting spinal deformities, including that of scoliosis, kyphosis, or lordosis in a patient's spine, so that the deformed spine portion can assume a normal degree of kyphosis and lordosis.

#### **Patentability of the Claimed Invention**

##### **A. Independent Claim 20**

Independent claim 20 recites a method for correcting spinal deformities by:

providing a correction device comprising an elongated rod, the elongated rod having a pre-contoured shape of a normal degree of kyphosis and lordosis of at least a portion of the patient's spine, the elongated rod comprising a superelastic material having a transition temperature ( $A_t$ ) within the range of human body temperature;

deforming the elongated rod to conform to a deformed portion of the patient's spine;

mounting the deformed elongated rod to the patient's spine including the deformed portion, whereby the deformed elongated rod is capable of applying a correction force having a predetermined amount to correct the deformed portion of the patient's spine, the correction force being generated by the superelastic material at the patient's body temperature and in an austenite phase of the superelastic material; and

maintaining the correction force at the predetermined amount until the deformed elongated rod resumes the pre-contoured shape to fully or substantially fully correct the spinal deformities;

the elongated rod is deformed before or simultaneously when the elongated rod is mounted to the patient's spine including the deformed portion.

Independent claim 20 is not taught by Justis because Justis, which concerns a different operation as applicants elaborated above, does not teach or suggest each and every claim feature of independent claim 20 based on the following detailed reasons.

Justis is silent about the transition temperature of the austenite phase (A) of the shape-memory material forming the spinal rod 302. Justis merely teaches that its spinal rod 302 is formed a shape-memory material that exhibits pseudoelastic behavior at about human body temperature. Such teachings of Justis in no way suggest that the transition temperature (A) of Justis's shape-memory material falls within the range of human body temperature. As one skilled in the art will appreciate, the shape-memory material of Justis's spinal rod 302 can have a transition temperature (A) well below human body temperature but exhibits pseudoelastic behavior at about human body temperature. In such a case, Justis's device is no different from a conventional device, such as that taught in Drewry. Accordingly, Justis does not teach that its spinal rod 302 comprises "a superelastic material having a transition temperature (A) within the range of human body temperature," as does the claimed superelastic rod recited in independent claim 20. Independent claim 20 is thus not taught by Justis for at least the above reasons.

Moreover, the Office Action misinterprets Justis to teach generating the correction force “in an austenite phase of the superelastic material” as recited in independent claim 20 (see page 3 of the Office Action). To the contrary, as Justis explicitly teaches, a restorative force is generated in a stress-induced martensitic state of the spinal rod 302 (see, e.g., col. 13, ll. 5-8 of Justis). Therefore, Justis does not teach “the correction force being generated by the superelastic material at the patient's body temperature and in an austenite phase of the superelastic material,” as is recited in independent claim 20. Independent claim 20 is thus not taught by Justis for the above additional reasons.

Furthermore, Justis does not teach mounting a deformed rod to the patient's spine. More specifically, Justis does not teach deforming its spinal rod 302 prior to mounting the rod 302 to the user's spinal column. In contrast, Justis explicitly teaches that the spinal rod 302 “is secured to the vertebrae V while in a substantially unstressed, initial configuration, where virtually all of the shape-memory material is in an austenitic state” (see col. 12, ll. 23-26 of Justis). In other words, Justis's spinal rod 302 is not deformed or otherwise deviated from its “initial” shape, when being mounted onto the user's spine.

Justis mentions that the spinal rod 302 may be pre-stressed prior to being secured to the vertebrae V, thus initially transforming a portion of the shape-memory material from austenite into SIM (see col. 12, ll. 32-35). Nevertheless, Justis does not teach that such pre-stressed spinal rod 302 is subject to shape change to deviate from its “initial” shape, much less to conform to a deformed portion of the user's spine, as does the claimed superelastic rod.

Accordingly, Justis does not teach “mounting the deformed elongated rod to the patient's spine,” as is recited in independent claim 20. Independent claim 20 is thus not taught by Justis for the above additional reasons.

In view of all the above reasons, independent claim 20 patentably distinguishes over Justis and is thus allowable. The claim rejection of independent claim 20 should be withdrawn.

B. Independent Claim 36

Independent claim 36 recites at least “the superelastic material having a transition temperature ( $A_f$ ) within the range of human body temperature” and that “the supporting member generates the correction force at the patient's body temperature and in an austenite phase of the superelastic material.”

Similar to the above reasons submitted in connection with independent claim 20, independent claim 36 is also allowable.

C. Independent Claim 46

Independent claim 46 recites at least “generating a correction force at the recipient's body temperature and in an austenite phase of the superelastic material” and “the superelastic material having a transition temperature ( $A_f$ ) within the range of human body temperature.”

Similar to the above reasons submitted in connection with independent claim 20, independent claim 46 is also allowable.

D. Dependent Claims 21-22, 28-29, 34-35, 37-39, 41-45, and 47-55

Claims 21-22, 28-29, 34-35, 37-39, 41-45, and 47-55 depend, directly or indirectly, from allowable independent claim 1, 36, or 46 and are thus each allowable therewith.

In addition, these dependent claims include features which serve to even more clearly distinguish the claimed invention over the prior art of record. For example, new claims 53-55 each recite that “the elongated rod is deformed by an orthopedic surgeon during an orthopedic procedure.” In contrast, the spinal rod 302 of Justis deforms after being mounted onto the user's spinal column and when the spinal column is subjected to the user's body movement. Therefore, new claims 53-55 are allowable for the above additional reasons.

## Conclusion

Based on all of the above, the present application is now in proper condition for allowance. Prompt and favorable action to this effect and early passing of this application to issue are respectfully solicited. Should the Examiner have any comments, questions, suggestions or objections, the Examiner is respectfully requested to telephone the undersigned in order to facilitate reaching a resolution of any outstanding issues.

No fees or charges are required at this time in connection with the subject application. If any fees or charges are required, they may be charged to the PTO Deposit Account No. 03-2412.

Respectfully submitted,  
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